STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
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Office of Pharmacy Services Prior Authorization Criteria for Chronic Hepatitis C Therapy

Effective 1/01/2017

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form
Preferred HepC Regimens (Attachment A)

Criteria for Approval

1) All documentation must be fully completed, including the patient consent form. The viral genotype and a fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**

2) Patient must have a documented **fibrosis level ≥ F3**; **AND**

3) Patient must be eighteen (18) years of age or older; **AND**

4) Selected treatment regimen must be prescribed by, or in conjunction with, a board-certified gastroenterologist, hepatologist or infectious disease physician; **AND**

5) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**

6) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 will be collected and made available to WV Medicaid to verify therapy success.

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A located at the end of this document. Initial approvals will be for a maximum of 12 weeks and require submission of the starting HCV RNA level.

- Additional therapy beyond 12 weeks may be requested by completing the Prior Authorization Continuation Request Form and is approvable only after receipt of a viral load indicating treatment efficacy as suggested by AASLD guidelines*.

- Emergency fills will NOT be granted under any circumstance.

***** AASLD guidelines recommend that quantitative HCV viral load testing be done after 4 weeks of therapy (TW4). If HCV RNA is detectable at week 4 of treatment, repeat quantitative HCV RNA viral load testing is recommended after 2 additional weeks of treatment. If the quantitative HCV viral load has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended.

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Additional Considerations

1) It is highly recommended that the patient be vaccinated against Hepatitis A and Hepatitis B.

2) Cirrhosis should be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging (MRI, ultrasound, or CT)
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

3) For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of the selected HCV regimen.

Criteria for Denial

1) Failure to report a genotype, fibrosis score or other significant omission from required documentation.

2) Any request falling outside the manufacturer guidelines for safe use.

3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.

4) Patient is taking a concomitant medication that has significant clinical interactions with the requested regimen.

5) Requests for continuation of coverage beyond 12 weeks will be denied if the patient's HCV RNA level has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter) or if the prescriber has not submitted or has not obtained a viral load prior to treatment week 12. **Denial of continuation due to lack of efficacy does not prevent the approval of an alternative regimen if indicated by AASLD guidelines.**

6) Coverage shall be for one <u>successful</u> course of therapy in a lifetime. Success of therapy shall be judged by undetectable quantitative HCV RNA levels measured at 12 weeks following completion of therapy (SVR12). If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

7) Lost or stolen medication replacement request will not be authorized.

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ATTACHMENT A: Accepted Regimens and Treatment Duration for Chronic Hepatitis C Therapy

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml→ Regimen 1 (HIV negative only) or 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million→ Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 8 or 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis→ Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin +protease inhibitor), no cirrhosis → Regimen 2 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), compensated cirrhosis → Regimen 5
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with therapy tailored based on these results
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants for both NS3 protease inhibitors and NS5A inhibitors is recommended with therapy tailored based on these results
	❑ Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, if ribavirin ineligible** → Regimen 3
	❑ Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
❑	**Genotype 1b**
	❑ Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1(HIV negative only) or 2 or 9 or 16
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 2 or 9 or 16
	❑ Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), no cirrhosis → Regimen 2 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 16
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), advanced fibrosis or compensated cirrhosis → Regimen 5
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data

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	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with treatment based on these results
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants is recommended with treatment based on these results
	❑ Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, or if ribavirin ineligible**→ Regimen 3
	❑ Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
❑	**Genotype 2**
	❑ Treatment naïve, no cirrhosis → Regimen 6
	❑ Treatment naïve, compensated cirrhosis → Regimen 6
	❑ Treatment experienced (PEG-IFN + ribavirin) → Regimen 6
	❑ Treatment experienced (sofosbuvir + ribavirin) → Regimen 7, if ribavirin ineligible** → Regimens 12
	❑ Decompensated cirrhosis → Regimen 7
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible**→ Regimen 12
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 19
❑	**Genotype 3**
	❑ Treatment naïve, with or without cirrhosis→ Regimen 6
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 6
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis → Regimen 7
	❑ Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis → Regimen 7
	❑ Decompensated cirrhosis → Regimen 7
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 12
❑	**Genotype 4**
	❑ Regardless of prior treatment, no cirrhosis → Regimen 2 or 8 or 11 or 16 or, if prior "on treatment virologic failure" with PEG-IFN/RBV (failure to suppress or breakthrough), 17
	❑ Treatment naïve, compensated cirrhosis → Regimen 2 or 8 or 11 or 16
	❑ Treatment experienced, compensated cirrhosis → Regimen 4 or 11 or 16 or, if prior "on treatment virologic failure" with PEG-IFN/RBV (failure to suppress or breakthrough), 17
	❑ Decompensated cirrhosis, no prior sofosbuvir →Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 14
❑	**Genotype 5**
	❑ Regardless of prior treatment → Regimen 2
❑	**Genotype 6**
	❑ Regardless of prior treatment → Regimen 2

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REGIMENS:

1. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks) ☐
2. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 84 days (12 weeks) ☐
3. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 168 days (24 weeks) ☐
4. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
5. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight based ribavirin for 168 days (24 weeks) ☐
6. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 84 days (12 weeks) ☐
7. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
8. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 84 days (12 weeks) ☐
9. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food X 84 days (12 weeks) ☐
10. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 168 days (24 weeks) ☐
11. Technivie (ombitasvir, paritaprevir, ritonavir 25/150/100 mg) + weight-based ribavirin for 84 days (12 weeks) ☐
12. Daklinza (daclatasvir) 60mg^ daily + Sovaldi (sofosbuvir) 400 mg daily X 168 days (24 weeks) ☐
13. Daklinza (daclatasvir) 60 mg^ + Sovaldi (sofosbuvir) 400 mg daily and low dose RBV# X 84 days (12 weeks) ☐
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin# for 84 days (12 weeks) ☐
15. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin# for 168 days (24 weeks) ☐
16. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks) ☐
17. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 112 days (16 weeks) ☐
18. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks) ☐
19. Sovaldi (sofosbuvir) 400 mg + low dose ribavirin #daily for 168 days (24 weeks) ☐

^ Dose of Daklinza (daclatasvir) MUST BE ADJUSTED with certain co-administered drugs (reduced to 30 mg daily with concurrent CYP3A4 inhibitors and increased to 90 mg daily with concurrent moderate CYP3A4 inducers)
# low dose ribavirin = 600 mg/day and increase as tolerated
¥ Genotype 1a polymorphisms at amino acid positions 28, 30, 31, or 93

NOTE: Please provide clinical rationale with the completed PA form if choosing a regimen that is beyond those found within the current guidelines, or if selecting regimens other than those outlined above.

Patients who are ineligible for treatment with ribavirin or interferon should have at least one of the following reasons documented:

❑ **Ribavirin-Ineligible****:

- ❑ History of severe or unstable cardiac disease
- ❑ Pregnant women and men with pregnant partners
- ❑ Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- ❑ Hypersensitivity to ribavirin
- ❑ Baseline platelet count <70,000 cells/mm3
- ❑ ANC <1500 cells/mm3
- ❑ Hb <12 gm/dl in women or <13 g/dl in men

Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced

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References

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Attachment A change Log:

Ver 2016.3C Created by Laureen Biczak (GHS) and edited by BMT 6/7/2016
Ver 2016.4D Created by Laureen Biczak (CHC)
Ver 2016.4E Created by Laureen Biczak (CHC)